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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,027	05/14/2001	Bernhard Hering	1432.05US02	7980

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/06/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/855,027		HERING ET AL.	
	Examiner		Art Unit	
	Michail A Belyavskyi		1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/31/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-44 and 65-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-44 and 65-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14, 15</u> . | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 3/31/03 (Paper No. 18), is acknowledged.

Claims 40-44 and 65-79 are pending.

In view of the amendment, filed 3/31/03 (Paper No. 18), the following objection and rejections remain:

- 2 . Applicant is advised that should claim 40 be found allowable, claim 67 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof essentially for the same reasons set forth in the previous Office Action, Paper No: 17, mailed 1/28/03

Applicant's arguments, filed 3/31/03 (Paper No. 18) have been fully considered, but have not been found convincing

Applicant asserted that a person of ordinary skill would interpret "within 96 hours of the pancreatic cell transplant" as meaning before or after the pancreatic cell transplant."

It is the Examiner position that in the instant case claim 40 recites "infusing donor cells within 96 hours of the pancreatic islet cell transplant" and claim 67 recites " donor cell infusion is performed after the pancreatic islet cell transplant". One of ordinary skill in the art would interpret the phrase "within 96 hours of the pancreatic islet cell transplant" as after but not before the pancreatic islet cell transplant. Moreover, according to Webster's Dictionary, the word "within" means **inside the fixed limits, not beyond**. The examiner can not understand how one of ordinary skill in the art would interpret the phrase "within 96 hours of the pancreatic cell transplant" as meaning before the pancreatic cell transplant " ?

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 40-44 and 65-79 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention essentially for the same reasons set forth in the previous Office Action, Paper No: 17, mailed 1/28/03

A. Claim 40 is indefinite and ambiguous in the recitation of "infusing donor cells" in line 6 ;

B. Claim 43 is indefinite and ambiguous in the recitation of "administering a cell pretreatment from the donor to the recipient". The characteristics and metes and bounds of "pretreatment" are unclear and indefinite and not defined by claims or specification as originally filed. Also, it is unclear who's cells donor or recipient are pretreated?

Applicant's arguments, filed 3/31/03 (Paper No. 18) have been fully considered, but have not been found convincing.

Applicant asserts that : (i) "infusing donor cells" is a clear terminology; (ii) administration of the cells is the cell pretreatment step, i.e. a step of pretreating a recipient with donor cells and that the donor cells are not pretreated.

Contrary to Applicant's assertion, it is the Examiner position that: (i) it is improper to recite "infusing donor cells". It is suggested that said phrase be changed to " performing a donor bone marrow cell transplant" for clarity and consistency with the disclosure of the specification. Moreover, pancreatic islet cells are also "donor cells" and it may be confusing as to what type of donor cells Applicant intended to infuse ? (ii) Claim 43 is indefinite and ambiguous in the recitation of "administering a cell pretreatment from the donor to the recipient" ; (iii) It is improper to recite "pretreating the recipient with pretreatment cells" in claim 68. It is unclear what Applicant means by "pretreatment cells" ?

It is suggested that claims 43 and 68 be re-written to incorporate Applicant's comments that administration of the cells is the cell pretreatment step, i.e. a step of pretreating a recipient with donor cells and that the donor cells are not pretreated.

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5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 42, 68, 71-73, 76,78 and 79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention essentially for the same reasons set forth in the previous Office Action, Paper No: 17, mailed 1/28/03

The claimed method of transplanting pancreatic islet cells from donor to a recipient, wherein :
1) donor chimerism level in the recipient of at least 15 % is achieved, claimed in Claim 42; 2) pretreating the recipient with pretreatment cell from the donor prior to the infusion of the donor cells, claimed in Claim 68; 3) administering the immune blockade treatment is accomplished by administering at least one of the compound selected from the group recited in Claim 71; 4) conditional treatment is started less than six days prior to the infusion of donor cells, claimed in Claim 72; 5) conditional treatment is started less than two days prior to the infusion of donor cells, claimed in Claim 73; 6) donor cell infusion includes administering the stem cells to the recipient on more than one day, claimed in Claim 76; 7) conditional treatment includes low-dose irradiation of less than 500 GY, claimed in Claim 78; 8) conditional treatment includes low-dose total body irradiation of less than 300 GY, claimed in Claim 79 represent a departure from the specification and the claims as originally filed and applicant has not pointed out where the support come from.

Applicant's arguments, filed 3/31/03 (Paper No. 18) have been fully considered, but have not been found convincing.

Applicant asserts that : (i) claim 42 is supported at page 44 line 22 to page 45, line 2; (ii) claim 68 is supported at page 34 lines 6-9; (iii) claim 71 is supported at page 33, lines 1-13; (iv) claims 72 and 73 are supported at page 32, lines 1-7; (v) claim 76 is supported on page 4, lines 13-15, page 8, lines 1-4, page 17, lines 4-9 page 30, lines 17-20 and page 32, lines 14-15; (vi) claims 78 and 79 are supported at page 18, line 12 and page 31, line 9-12.

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Contrary to Applicant's assertion: (i) page 44, line 22 to page 45, line 2 does not support "a donor chimerism level in the recipient of at least 15 % is achieved", recited in claim 42. The passages pointed by Applicant only support "at least 1% mixed chimerism is induced for most application. Preferably at least 10% mixed chimerism is induced; (ii) page 34, lines 6-9 does not support "pretreating the recipient with pretreatment cells from donor prior to the infusion of the donor cells" as recited in the claim 68. The passages pointed by Applicant only support pretreatment of donor cell. There is no indication or support for "pretreating the recipient with pretreatment cells; (iii) page 33, lines 1-13 does not support all compounds for immune blockade treatment recited in claim 71, in particular for anti-CD40L, sirolimus and compounds that inhibit the binding of B7 to CD28; (iv) page 32, lines 1-7 does not support "conditional treatment is started less than six days prior to the infusion" recited in claim 72 or "conditional treatment is started less than two days prior to the infusion, recited in claim 73. The passages pointed by Applicant only support 'the conditioning treatment is accomplished less than two weeks and optimally less than five days before the bone marrow transplantant; (v) page 4, lines 13-15, page 8, lines 1-4, page 17, lines 4-9 page 30, lines 17-20 and page 32, lines 14-15 does not support 'administering the stem cells to the recipient on more than one day". The passages pointed by Applicant only support administering stem cells to the recipient; (vi) page 18, line 12 and page 31, line 9-12 does not support "low dose irradiation of less than 500 Gy", recited in claim 78 or "low dose irradiation of less than 300 Gy", recited in claim 79. The passages pointed by Applicant only support low doses of TBI or irradiation at doses significantly less than practiced in conventional conditioning treatments.

7. No claim allowed

8. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
May 5, 2003


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